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10/041,856	01/07/2002	Susan Slaugenhaupt	13572-105039	5418

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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/041,856	SLAUGENHAUPT ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007 and 10 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,68,81-84,87-90,100 and 101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *61 and 68* is/are allowed.

6)☒ Claim(s) *81-84,87-90,100 and 101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/2007*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *3/7/07, 3/14/07* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the reply filed on April 10, 2007 and February 28, 2007. Applicant's arguments and amendments to the claims have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn.

Acknowledgement is made of the Declarations filed under 37 CRF 1.131 and 1.132, submitted February 28, 2007. In view of these declarations and the amendments to the claims filed on April 10, 2007, the previous grounds of rejection have been obviated.

However, this Office action contains new grounds of rejection necessitated by Applicant's amendments to the claims. This action is made Final.

2. Claims 61, 68, 81-84, 87-90, 100 and 101 are pending and have been examined herein.

Information Disclosure Statement

3. In the information disclosure statement filed on February 28, 2007, the citations to "Complaint for Civil Action No. 06 CV 6443" and "Notice of Voluntary Dismissal of Civil Action No. 06 CV 6443" are not in compliance with the requirements of 37 CFR 1.98. As set forth in MPEP 609, non-patent publications may be listed in an IDS if they are identified by "publisher, author (if any), title, relevant pages of the publication, date, and place of publication." In the present situation, the above noted citations do not appear to have been published and thereby do not include a publisher, publication date or place of publication.

Accordingly, while these documents have been considered, they have been lined through on the PTO 1449 form.

Claim Objections

4. Claim 101 is objected to because the claim refers back to the oligonucleotide probe of claim 100, whereas claim 100 is drawn to a kit comprising an isolated oligonucleotide probe. As stated in MPEP 608.01(n), "The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim... On the other hand, if claim 1 recites a method of making a specified product, a claim to the product set forth in claim 1 would not be a proper dependent claim since it is conceivable that the product claim can be infringed without infringing the base method claim if the product can be made by a method other than that recited in the base method claim." In the present situation, the oligonucleotide probe of claim 101 does not include every limitation of the claim from which it depends (i.e., claim 10) because claim 101 does not require that the oligonucleotide probe is present in a kit for the detection of a mutation associated with FD in a sample from a human subject. This objection may be overcome by amendment of claim 101 to refer to the kit of claim 100, wherein said isolated oligonucleotide probe consists of 16 nucleotides.

Claim Rejections - 35 USC § 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81-84, 87-90, 100 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 81-84, 87-90, 100 and 101 are indefinite over the recitation of "the FD" mutation because this phrase lacks proper antecedent basis since the claims do not previously refer to a FD mutation. Further, while the specification (pages 2-3) defines what is in intended to be encompassed by a FD1 mutation and a FD2 mutation, the specification does not define what is intended to be encompassed by "the FD" mutation at position 33,714 or 34,201. This rejection may be overcome by amendment of the claims to recite "a FD1 mutation at position 34,201 of SEQ ID NO: 1" and "a FD2 mutation at position 33,714 of SEQ ID NO: 1."

Claims 87-90, 100 and 101 are indefinite over the recitation of "nucleotide corresponding to." Corresponding is not an art recognized term to describe the relationship between a nucleotide and a nucleic acid sequence. It is not clear as to whether a corresponding nucleotide refers to a nucleotide which is at the same position as position 33,714 or 34,201 in the sequence of SEQ ID NO: 1 or to a nucleotide which is at a nearby position (e.g., position 33,715 or 33,720 etc) or if this refers to a similar nucleotide (e.g., an A in place of a G) or the same nucleotide at any position in SEQ ID NO: 1. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. Patent No. 5,891,719).

Cohen teaches an oligonucleotide encoding amino acids 683-697 of SEQ ID NO: 2 therein (see claim 10 and col. 4-5). This oligonucleotide consists of nucleotides 2047-2091 of SEQ ID NO: 1 of the IKAP gene disclosed by Cohen. The oligonucleotide is identical to the nucleotide fragment of present SEQ ID NO: 1 consisting of nucleotides 33,668 to 33,718. Thereby, the oligonucleotide of Cohen consists of 16 or more contiguous nucleotides of present SEQ ID NO: 1, from within the region of nucleotides 32,642 to 36,846 of SEQ ID NO: 1, and includes nucleotide position of 33,714 of present SEQ ID NO: 1. Since the oligonucleotide of Cohen includes nucleotide 33,714 of present SEQ ID NO: 1, this oligonucleotide has the property of being suitable for the detection of the FD2 mutation at position 33,714 of SEQ ID NO: 1.

Regarding claim 100, in the absence of any recitation in the claims or any direction provided in the specification to the contrary, the recitation of "kit" reads on component parts capable of being assembled or a plurality of elements grouped together. Accordingly, the word "kit" does not impart any additional special structural or functional features which distinguishes the claimed kit over the composition of Cohen

comprising IKAP oligonucleotide. Further, as noted in the MPEP 211.02, " a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Additionally, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." In the present situation, the claim language of "for the detection of a mutation associated with Familial Dysautonomia in a sample from a human subject," merely sets forth the intended use or purpose of the claimed kits, but does not further limit the structure of the claimed product. Thereby, the compositions of Cohen comprising the oligonucleotide as defined above anticipate the claimed "kits" comprising an isolated oligonucleotide probe.

Response to Remarks / Arguments:

In the responses filed February 28, 2007 and April 10, 2007, it is stated that the previous rejection of the claims as anticipated by Cohen is not applicable to the currently pending claims. However, for the reasons stated above, the newly added claims are anticipated by the teachings of Cohen.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 84 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

Cohen teaches an oligonucleotide encoding amino acids 683-697 of SEQ ID NO: 2 therein (see claim 10 and col. 4-5). This oligonucleotide consists of nucleotides 2047-2091 of SEQ ID NO: 1 of Cohen. The oligonucleotide is identical to the nucleotide fragment of present SEQ ID NO: 1 consisting of nucleotides 33,668 to 33,718. Thereby, the oligonucleotide of Cohen consists of 16 or more contiguous nucleotides of present SEQ ID NO: 1, from within the region of nucleotides 32,642 to 36,846 of SEQ ID NO: 1, and includes nucleotide position of 33,714 of present SEQ ID NO: 1. The reference (Table 1) teaches that amino acids 683-697 and flanking amino acids define functional

domains of the IKAP protein. Further, Cohen (col. 5) teaches nucleic acid hybridization probes and primers consisting of the IKAP sequences of SEQ ID NO: 1 therein. Cohen states that such primers and probes may consist of at least 12 nucleotides of SEQ ID NO: 1 therein and teaches that the primers and probes are selected so that they specifically hybridize to sequences complementary to SEQ ID NO: 1 therein. Cohen (Table 2) exemplifies oligonucleotides that hybridize to the complement of the IKAP gene, but does not specifically exemplify oligonucleotides consisting of 16 nucleotides that span the region that includes nucleotide 33,714 of present SEQ ID NO: 1 (i.e., nucleotide 2087 of Cohen).

However, designing primers and probes which are equivalents to those taught in the art is considered to be conventional in the art and well within the skill of the art. The parameters and objectives involved in the selection of primers and probes were well known in the art at the time the invention was made. Moreover, software programs were readily available which aid in the identification of conserved and variable sequences and in the selection of optimum primer and probes. The prior art is replete with guidance and information necessary to permit the ordinary artisan to design additional primers for the amplification of IKAP sequences and probes for the detection of IKAP sequences. Additionally, Cohen specifically provides the motivation to obtain oligonucleotides consisting of at least 12 nucleotides of SEQ ID NO: 1 therein and to use the oligonucleotides as primers or probes for the amplification and detection of IKAP sequences. In view of the teachings of Cohen of the desire to obtain primers and probes consisting of at least 12 nucleotides of SEQ ID NO: 1 therein and the disclosure

of Cohen of nucleic acids that specifically include nucleotide position 2087 (i.e., nucleotide 33,714 of present SEQ ID NO: 1), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have generated additional primers and probes, including the claimed oligonucleotides of 16 nucleotides comprising the region of SEQ ID NO: 1 of Cohen including nucleotide 2087. One would have been motivated to have generated such oligonucleotides in order to have provided additional oligonucleotides that could function as primers and probes for amplifying and detecting IKAP nucleic acids.

Regarding claim 101, in the absence of any recitation in the claims or any direction provided in the specification to the contrary, the recitation of "kit" reads on component parts capable of being assembled or a plurality of elements grouped together. Accordingly, the word "kit" does not impart any additional special structural or functional features which distinguishes the claimed kit over the composition of Cohen comprising IKAP oligonucleotide. Further, as noted in the MPEP 211.02, " a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Additionally, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a

claim limitation." In the present situation, the claim language of "for the detection of a mutation associated with Familial Dysautonomia in a sample from a human subject," merely sets forth the intended use or purpose of the claimed kits, but does not further limit the structure of the claimed product.

8. Claims 61 and 68 are allowed. It is noted that the specification at pages 2 to 3 defines a "FD1" mutation as the major haplotype wherein a thymine nucleotide located at bp 6 of intron 20 in the IKBKAP gene is replaced with a cytosine. A "FD2" mutation is the minor haplotype wherein a guanine nucleotide at bp 2397 (bp 73 of exon 19) is replaced with a cytosine nucleotide, leading to an arginine to proline missense mutation at position 696 of the IKBKAP protein. However, it is suggested that Applicants amend the claims to include these specific definitions for the FD1 and FD2 mutations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/
Primary Examiner, Art Unit 1634